# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

Case No. 08 CV 1490-AKH

DREW SCIEN' ] vs.	TIFIC, INC., Plaintiff,	))))
	ΓΕCHNOLOGIES, INC,. Defendants.	))))

# POINTCARE TECHNOLOGIES, INC.'s

# ANSWER, COUNTERCLAIMS

- and -

#### JURY TRIAL DEMAND

Defendant PointCare Technologies, Inc. ("PointCare") hereby answers the complaint of Drew Scientific., Inc. ("Drew") as follows:

- 1. PointCare is without knowledge or information sufficient to form a belief as to the allegations in this paragraph and, accordingly, such allegations are denied.
  - 2. Admitted.
  - 3. This paragraph contains a legal conclusion to which no response is required.
- 4. PointCare is without knowledge or information sufficient to form a belief as to the allegations that Drew conducts business activities within this District. PointCare denies that it conducts business activities in this District. The parties' Manufacturing, Distribution and Co-Marketing Agreement dated June 2006 is a writing that speaks for itself. To the extent that this paragraph contains a legal conclusion, no response is required.
- 5. This paragraph merely characterizes the relief sought in this action. PointCare denies that Drew is entitled to the requested relief.

# **FACTUAL ALLEGATIONS**

- 6. PointCare admits that the Agreement was entered into in June 2006. In further answering, PointCare states that the Agreement is a writing that speaks for itself.
- 7. Answering the first, second, fifth, sixth and seventh sentences of this paragraph, the Agreement is a writing that speaks for itself. PointCare is without knowledge or information sufficient to form a belief as to the allegations in the third sentence of this paragraph. PointCare admits that Drew has shared certain of its marketing plans and sales strategies with PointCare. PointCare denies the allegations in the eight sentence of this paragraph.
- 8. Answering the first, second and fifth sentences of paragraph 8, the Agreement is a writing that speaks for itself. PointCare is without knowledge or information sufficient to form a belief as to the allegations in the third sentence of paragraph 8 of the Complaint. PointCare denies the remaining allegations in this paragraph.
- 9. PointCare admits that it has received approval by the Food and Drug Administration for the NP platform, and that PointCare used Drew's hematology system to produce some of the hematology data relied upon in PointCare's FDA submissions. PointCare denies the remaining allegations in Paragraph 9 of the Complaint.
- 10. PointCare denies the allegations in the first, fourth, fifth, sixth and seventh sentences sentence of this paragraph. PointCare admits the second sentence of this paragraph. PointCare admits that Drew fell behind the projected timeline, but denies the remaining allegations in the third sentence of this paragraph. PointCare is without knowledge or information sufficient to form a belief as to the allegation that Drew thought the parties were working cooperatively through the issues until the American Association for Clinical Chemistry ("AACC") convention of July 15-19, 2007 and, accordingly, such allegations are denied.

PointCare admits that PointCare's President and CEO Petra Krauledat complained to the President and CEO of Escalon Medical Corp. ("Escalon"), Drew's corporate parent, at the AACC convention and she followed up the oral complaint with an e-mail dated September 13, 2007.

- 11. PointCare is without knowledge or information sufficient to form a belief as to the allegation that Escalon's President and CEO conducted an investigation and, accordingly, this allegation is denied. PointCare admits that Escalon's President and CEO furnished a reply on October 3, 2007. PointCare admits that PointCare made a proposal to Drew on or about October 26, 2007, but denies Drew's characterization of the proposal.
- 12. PointCare admits the allegations in the first sentence of this paragraph. PointCare is without knowledge or information sufficient to form a belief as to the allegation that Drew's distributor denied that such a tender was taking place and, accordingly, this allegation is denied. PointCare admits that Drew requested from PointCare specific information about the purported tender and an appropriate certification of the NP technology.
- 13. PointCare denies the allegations in the first sentence of this paragraph. PointCare admits that Escalon's President called on October 18. PointCare is without knowledge or information sufficient to form a belief as to the reasons that Escalon's president made the call, and, accordingly, such allegations are denied. PointCare admits that PointCare's President sent an e-mail to Escalon's President on October 26.
- 14. PointCare admits that it looked for new investors or ways to gain additional capital in or about Fall 2007 but denies it was experiencing financial distress. PointCare is without knowledge or information sufficient to form a belief as to the allegations in the second sentence of this paragraph. PointCare denies the remaining allegations of this paragraph 14.

- 15. PointCare admits that it declined to return an NP device to Drew that Drew had sent to PointCare, at its request, so that PointCare could perform a software modification, but PointCare denies the remaining allegations in the first sentence of this paragraph. PointCare is without knowledge or information sufficient to form a belief as to the allegations in the second sentence of this paragraph. PointCare admits that when it requested return of the machine for a software upgrade, it indicated it intended to re-deliver the instrument to Drew. PointCare admits that it informed Drew on or about November 1 that at the direction of PointCare's President, the NP device would not be returned to Drew. PointCare denies that its action violated the explicit or implicit cooperation provisions of the Agreement.
- 16. PointCare admits that its President sent Drew an email, and that the email is a document that speaks for itself. PointCare denies that its conduct violated the Agreement.
- 17. PointCare admits that Drew sent an e-mail on or about November 7, and that the email is a document that speaks for itself. PointCare admits that at a November 8 meeting, PointCare's President proposed a modification to the Agreement. PointCare denies the remaining allegations in this paragraph.
  - 18. Admitted.
- 19. PointCare admits that it gave Drew the requisite default notice on or about November 9, 2007 based on Drew's material breach of the Agreement. The notice is a document that speaks for itself. PointCare admits that the parties had further communications regarding Drew's request for an NP device. PointCare denies the remaining allegations in this paragraph.
- 20. PointCare admits that it removed references to Drew on its website on or about November 9. PointCare denies the remaining allegations in this paragraph.

- 21. PointCare admits that its default notice gave Drew sixty days to cure its defaults. PointCare is without knowledge or information sufficient to form a belief as to the allegations in the second sentence of this paragraph. PointCare admits that Drew sent correspondence to PointCare on December 7, 2007, and that the correspondence is a document that speaks for itself.
- 22. PointCare admits that Drew has offered to arrange for the shipment of an HT device to PointCare, and for consultation between PointCare and Dr. Chow with respect to his report. PointCare admits that it declined to take delivery of an HT device. PointCare denies the remaining allegations in this paragraph.
- 23. PointCare admits that Drew eventually provided PointCare with Dr. Chow's test report, after repeated requests, and that Drew offered to set up a teleconference with Dr. Chow. PointCare denies the remaining allegations in this paragraph.
- 24. PointCare admits that it received the Chow report, that Drew offered to set up a teleconference with Dr. Chow. PointCare admits that it declined delivery of the HT platform. PointCare admits that it advised Drew that the Agreement between the parties was terminated for failure to cure a material breach timely development of the HT platform. PointCare denies the remaining allegations in this paragraph.
- 25. PointCare admits that it declined several requests to return an NP device to Drew that Drew had sent to PointCare. PointCare denies the remaining allegations in this paragraph.
- 26. PointCare admits that it has received FDA approval of the NP device, and that it submitted data using one of Drew's machines. PointCare denies the remaining allegations in this paragraph.
- 27. PointCare denies the allegations in the first two sentences of this paragraph.

  PointCare is without knowledge or information sufficient to form a belief as to the allegations

5

that Drew has exhibited a prototype of the NP platform at trade shows on several occasions and, via its efforts, generated a good deal of interest.

- 28. Denied.
- 29. Denied.
- 30. PointCare admits that, given its proper termination of the parties' Agreement, PointCare intends to exercise its right to sell its products worldwide, including through distributors in territories formerly assigned to Drew under the Agreement. PointCare denies the remaining allegations in this paragraph.

# FIRST CAUSE OF ACTION

# **BREACH OF CONTRACT – DAMAGES**

- 31. PointCare repeats and incorporates by reference paragraphs 1 to 30 as if fully set forth herein.
  - 32. This paragraph contains a legal conclusion to which no response is required.
  - 33. Denied.
  - 34. Denied.
  - 35. Denied.

# **SECOND CAUSE OF ACTION**

# **BREACH OF CONTRACT – PERMANENT INJUNCTION**

- 36. PointCare repeats and incorporates by reference paragraphs 1 to 35 as if fully set forth herein.
  - 37. This paragraph contains a legal conclusion to which no response is required.
  - 38. Denied.
  - 39. Denied.

40. Denied.

#### THIRD CAUSE OF ACTION

# **DECLARATORY JUDGMENT**

- 41. PointCare repeats and incorporates by reference paragraphs 1 to 40 as if fully set forth herein.
- 42. PointCare admits that an actual controversy exists between Drew and PointCare regarding PointCare's termination of the Agreement but denies PointCare has engaged in misconduct.
  - 43. PointCare denies that Drew is entitled to the requested declaration.

### **FOURTH CAUSE OF ACTION**

# **SPECIFIC PERFORMANCE**

- 44. PointCare repeats and incorporates by reference paragraphs 1 to 43 as if fully set forth herein.
  - 45. This paragraph contains a legal conclusion to which no response is required.
  - 46. Denied.
  - 47. Admitted.
- 48. PointCare admits that, with respect to completion of the HT project, PointCare is the sole source provider of the CD4Sure assay, controls its patent rights and possesses the expertise relative to the assay. PointCare further admits that it would be able to complete the necessary compatibility testing with little or no capital cost if Drew were to provide PointCare with a completed HT instrument ready for clinical evaluations for the purpose of FDA approval. PointCare denies the remaining allegations in this paragraph.
  - 49. Denied.

# **FIFTH CAUSE OF ACTION**

# FRAUDULENT INDUCEMENT

- 50. Denied.
- 51. Denied.
- 52. Denied.
- 53. Denied.

# SIXTH CAUSE OF ACTION

# **CONVERSION**

- 54. PointCare repeats and incorporates by reference paragraphs 1 to 53 as if fully set forth herein.
  - 55. Denied.
  - 56. Denied.

# **SEVENTH CAUSE OF ACTION**

# **CONSTRUCTIVE TRUST**

- 57. PointCare repeats and incorporates by reference paragraphs 1 to 56 as if fully set forth herein.
  - 58. Denied.
  - 59. Denied.
  - 60. Denied.

# **EIGHTH CAUSE OF ACTION**

# TORTUOUS [sic] INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

61. PointCare repeats and incorporates by reference paragraphs 1 to 60 as if fully set forth herein.

- 62. This paragraph contains a legal conclusion to which no response is required.
- 63. Denied.
- 64. Denied.

# **NINTH CAUSE OF ACTION**

# BREACH OF THE IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

- 65. PointCare repeats and incorporates by reference paragraphs 1 to 64 as if fully set forth herein.
  - 66. This paragraph contains a legal conclusion to which no response is required.
  - 67. Denied.
  - 68. Admitted.
  - 69. Denied.

#### **FURTHER DEFENSES**

PointCare asserts the following affirmative and other defenses to the complaint, and in that regard, repeats and incorporates paragraphs 1 through 69 above, and further alleges and asserts as follows:

#### **FIRST DEFENSE**

Drew has failed to state a cause of action in the complaint for which relief can be granted. Federal Rule of Civil Procedure 12(b)(6).

# **SECOND DEFENSE**

Drew is barred from recovery because PointCare has fulfilled all of its obligations under any contract between the parties.

# THIRD DEFENSE

Drew is barred from any recovery under the contract because of Drew's material breaches of the contract.

#### FOURTH DEFENSE

Drew is barred from any recovery under the contract because PointCare properly terminated the contract pursuant to Section 6.9 of the contract.

#### FIFTH DEFENSE

Drew is barred from any recovery under the contract because it failed to perform conditions precedent, specifically, Drew failed to successfully complete development and marketing of the HT system, upon which Drew's non-exclusive worldwide distribution rights to the NP system were contingent.

#### **SIXTH DEFENSE**

If Drew suffered any damages, its damages are the result of its own conduct.

#### SEVENTH DEFENSE

Drew is barred from any recovery on the basis of unclean hands.

## **EIGHTH DEFENSE**

Drew is barred from any recovery on the basis of laches, waiver and/or estoppel.

# **NINTH DEFENSE**

Drew failed to mitigate its damages.

#### TENTH DEFENSE

Any amounts claimed in the Complaint are set off or exceeded by the amounts of claims of PointCare in its counterclaims.

# **ELEVENTH DEFENSE**

Count V (Fraudulent Inducement) is barred by Drew's failure to plead fraud with

particularity as required by Fed. R. Civ. P. 9(b).

#### TWELFTH DEFENSE

The action filed by Drew is frivolous, wholly unsubstantial and not advanced in good faith, and PointCare is entitled to recovery of all costs, expenses, and attorney's fees associated with the defense of this action.

## THIRTEENTH DEFENSE

As a further defense, PointCare incorporates its Counterclaim herein.

#### **COUNTERCLAIMS**

#### Introduction

PointCare brings its counterclaims to recover damages caused by Drew's of the parties' contract. PointCare also seeks a declaration (i) that Drew materially breached the parties' Agreement, Drew failed to cure its breaches, and PointCare was justified in terminating the Agreement and (2) that Drew has no rights with respect to PointCare's proprietary AIDS diagnostic system and chemical reagents (the NP platform and CD4 assay).

#### **Parties**

PointCare is a company organized and existing under the laws of the 1. Commonwealth of Massachusetts, with a principal place of business at 181 Cedar Hull Street. Marlborough, Massachusetts. PointCare is a small, privately held, FDA registered, ISO certified, medical diagnostics company. PointCare is devoted to developing and providing better, more affordable, and more accessible medical diagnostic care to disadvantaged populations in the United States and around the world, especially in areas where people would otherwise not have access to such care.

2. On information and belief, Drew is a company organized and existing under the laws of the State of Texas, with a principal place of business at 4230 Shilling Way, Dallas, Texas.

# The Agreement

The Agreement between PointCare and Drew became effective on or about June5, 2006. See the Agreement, Exhibit 1 to the Complaint.

# Drew's Responsibilities

- 4. Under the Agreement, Drew agreed to modify its medical diagnostic platform, specifically, the Excell 22 hematology platform, to accommodate PointCare's proprietary chemical reagents, specifically, the CD4 Lymphocyte Enumeration Assay, CD4SURE.
- 5. Drew agreed to manufacture two versions of its platform, one to be sold by Drew, and another to be sold by PointCare. See Agreement at § 1.1, page 1. Together, these platforms are known as the "high throughput" or "HT" platforms.
- 6. Pursuant to § 1.3.2 of the Agreement, Drew was responsible for ensuring that the HT instrumentation platform it was required to develop met the specifications established under the Agreement as well as all legal and regulatory requirements, including relevant FDA requirements for approval.
  - 7. Drew was responsible for all expenses incurred in these efforts.
- 8. Attachment 1 to Annex 1 of the Agreement sets forth the development timetable for the HT instrumentation platform, to which Drew was required to adhere.
  - 9. Drew did not adhere to this timeline.
- 10. The timeline sets forth three deadlines for release to market of the HT, the earliest of which was January 5, 2007, the latest of which was July 27, 2007.

- 11. Drew met none of these deadlines.
- When the parties negotiated the Agreement, PointCare notified Drew of the requirements for modifying Drew's Excel 22 instrument to accommodate the PointCare CD4SURE assay. Drew's engineering team reviewed these specifications, agreed and initialed them, and the specifications were incorporated into the Agreement at Annex 1. Attachment 2 to Annex 1 sets forth the specifications and performance parameters for the HT instrumentation platforms to be developed by Drew.
- 13. Pursuant to the timetables set forth in Annex 1 to the Agreement, Drew was required to substantially modify, and add new hardware to, its Excell 22 hematology platform to be compatible with PointCare's CD4 assay.
  - 14. Drew never met this obligation.

#### PointCare's Responsibilities

- 15. Pursuant to § 1.3.1 of the Agreement, PointCare was responsible for ensuring that its CD4SURE assay and the software compatible with the HT instrument, the NP instrument and the compatible CD4 assay would meet the specifications established under the Agreement and all legal and regulatory requirements, including relevant FDA requirements for approval.
  - 16. PointCare was responsible for all expenses incurred in these efforts.
- 17. Attachment 3 to Annex 1 sets forth the specifications for PointCare's CD4SURE assay. Pursuant to the timetables set forth in Annex 1, PointCare was required to modify its CD4SURE reagents and software to be compatible with the HT instrumentation platform. PointCare met this obligation.

- 18. The Agreement also provided that PointCare would develop and manufacture (with a third-party medical device manufacturer) a "Near Patient" or "NP" instrumentation platform. Agreement at page 2.
- 19. The specifications and performance parameters for the NP instrumentation platform and assay were spelled out in Annex 2 of the Agreement. The responsibilities and allocation of costs for the NP instrumentation platform and assay were also set forth in Annex 2.
- 20. Pursuant to the specifications set forth in Annex 2, PointCare was required to develop, manufacture and get FDA approval for the NP instrumentation platform and the CD4 assay compatible with the NP instrument.
  - 21. PointCare met this obligation.
- 22. Pursuant to § 1.1 (at page 2) of the Agreement, Drew was to receive "non-exclusive worldwide distribution rights for such NP platform" developed by PointCare. However, "[s]uch distribution rights will be conditional upon the successful development and marketing of the HT platform."
  - 23. Drew did not successfully develop the HT platform.
  - 24. Drew did not successfully market the HT platform.
- 25. Therefore, Drew did not perform these condition precedent to its obtaining non-exclusive worldwide distribution rights for the NP platform.
- 26. Sections 5.1 and 5.2 of the Agreement provide that each party's intellectual property rights remain their own, as do all future developments of those rights. Section 5.3 provides that if any intellectual property is jointly developed by the parties during the term of the Agreement, such a joint invention must be described in writing by the parties within ten business

days of the invention. Neither party has made a claim for any jointly developed inventions under § 5.3.

- 27. Section 6.9 of the Agreement provides that "[e]ither Party may terminate this Agreement: (a) in the event of a material breach by the other Party of any of the terms and conditions of the Agreement...by giving the other Party written notice of such breach, and provided that such breach shall not have been cured within sixty (60) days of such notice...."
- 28. Section 7 provides that "[e]ach Party shall maintain in confidence both the terms of this Agreement and any information received from the other Party in writing during the term of this Agreement and shall neither publish, disseminate nor disclose such information...."

# PointCare's Performance Under The Agreement

- 29. According to the Agreement, PointCare was responsible to modify its CD4 assay and software so that it is compatible with the Drew Excel 22 substantially modified hardware.
- 30. PointCare completed all work on its modified CD4 assay development by November 21, 2006.
- 31. PointCare reported the successful results to Drew in November 2006. Drew did not question or dispute the results.
- 32. PointCare continued forward after completing all its development work on the modified CD4 assay. In or about April of 2007, PointCare, pursuant to FDA requirements, completed the package design (of a container that would maintain the stability of the CD4 assay's chemical reagents in harsh environments) and labeling of the test kit (specifying intended use and specifications of assay) and manufactured three reagent lots and began stability studies for all fully manufactured test components. With that, PointCare had complied with all FDA

not do until Drew completed development of the HT instrument.

requirements and was ready to begin clinical evaluations to obtain FDA approval, which it could

- 33. PointCare was fully prepared to test Drew's HT instrument as soon as Drew delivered it to PointCare with the FDA required testing data, which Drew never did.

  Specifically, PointCare kept reagents at the ready for testing to obtain FDA approval of the CD4 test at all times until termination of the Agreement.
- 34. The NP instrument, and the CD4 test compatible with it, was developed by PointCare and C2, its third party medical device manufacturer, not Drew. Drew did not contribute to the development of the NP, except to the limited extent that PointCare used a Drew commercially available, FDA approved instrument as a reference method to gather certain data submitted to the FDA for certification.

#### **Drew's Failure of Performance**

- 35. As an initial step toward its ultimate obligation of delivering an HT instrument ready to go to market, Drew developed a pre-prototype HT instrument by October 2006.
- 36. Thereafter, as noted above, Drew was responsible (i) to turn the pre-prototype, manually operated HT instrument into a fully automated instrument, (ii) manufacture the instrument, and (iii) obtain FDA approval for the HT instrument.
- 37. Drew was required to supply one such fully developed instrument to PointCare so that PointCare could use it to obtain data required for FDA approval for its CD4 assay on the HT instrument.
- 38. The first step in Drew's turning the pre-prototype, manually operated HT instrument into a fully automated instrument was integrating the components of the system hardware.

- 39. By December 2006, Drew experienced difficulties when trying to achieve this integration.
- 40. In a voluntary good faith effort to assist Drew in meeting its own obligations. PointCare sent an engineer at its expense to reside at Drew from late January 2007 through early March 2007 to assist Drew engineers in identifying the root cause of the observed problems. This effort was hindered because Drew lacked basic cell analysis equipment, tools that were necessary to determine the root causes of the problems..
- Therefore, in a further voluntary good faith effort to assist Drew in meeting its 41. own obligations, PointCare recommended the troubleshooting work be transferred to PointCare, where the necessary equipment was at hand.
- Drew accepted PointCare's offer to assist it in determining the root causes of the 42. hardware integration problems and Drew sent an HT instrument to PointCare. Despite PointCare's good faith efforts to assist Drew in overcoming the hardware integration problem's with Drew's HT instrument, Drew failed to solve those problems to day, as discussed in further detail below.
- 43. By mid-March 2007, PointCare isolated the first hardware integration problem, with involved the HT's fluidic subassembly (the component that mixes the blood sample with chemical reagents and moves this mixture within the instrument to where it is analyzed).
  - 44. PointCare promptly reported this finding to Drew.
- 45. This problem with the HT's fluidic subassembly prevented the machine from processing more than three samples before breaking down. (The system's specifications called for it to process a minimum of 100 samples per day in a fully automated fashion).

- 46. It was not until months later, in or about June 22, 2007, that Drew belatedly acknowledged the problem with the HT's fluidic subassembly.
- 47. Drew failed to solve the problem until on or about November 19, 2007, when Drew reported to PointCare that the problem finally was solved. Even then, Drew failed to provide PointCare with test data demonstrating that Drew, in fact, had solved the problem.
- 48. By mid-April 2007, PointCare had isolated an additional hardware integration problem, which involved the HT's optics subassembly (the component of the HT instrument that counts the blood cells in the samples being tested). This problem prevented Drew from any further progress toward integrating the HT system hardware.
  - 49. PointCare promptly informed Drew of this problem.
  - 50. Drew determined that the problem was that the optics subassembly was unstable.
- 51. On Drew's instructions, PointCare manually corrected the instability as a short term fix.
  - 52. By August 2007, Drew finally isolated the cause of the unstable optics.
- 53. On information and belief, as late as November 2007, Drew was still working on the problem and had yet to integrate a solution into the system hardware.
- 54. On information and belief, as late as December 11, 2007, Drew was making experimental hardware changes to the HT instrument. Drew did not disclose this information to PointCare.
- 55. Despite multiple requests, Drew failed (until October 2007) to communicate to PointCare an expected project completion date after Drew failed to perform according to the agreed-upon timeline in Annex 1 to the Agreement.

- 56. Pursuant to Annex 3 to the Agreement, the lead marketer is required to give the other party a detailed sales plan for its territories. Drew never gave PointCare a sales plan; this despite the fact that Dr. Krauledat and others at PointCare repeatedly asked Drew for a sales plan. PointCare, in contrast, gave its sales plan to Drew in April of 2007.
- 57. As early as February 2007, during a visit to the Drew facility in Dallas, PointCare President Petra Krauledat met with Richard DePiano, President and CEO of Drew's corporate parent, Escalon Medical Corp., where she voiced her concern about Drew's ability to fulfill its obligations regarding the engineering of the HT instrument. Mr. DePiano fully agreed with her concerns and proposed a merger of the two companies, where one of the merger goals was to increase the notoriously slow pace of Drew engineering and raise standards of their technical output to the standard of PointCare.
- During the entire merger negotiations from February to May 2007, Mr. DePiano 58. frequently voiced his own frustration about the slow and casual attitude of Drew engineering. Mr. DePiano and Ms. Krauledat discussed multiple ideas about changing this problem, including moving the Drew engineering group to the PointCare facilities or the replacement of the entire Drew engineering development group with only the one exception of the software engineer.
- 59. By September of 2007, there were significant delays with respect to Drew's progress on the HT due to problems caused by Drew. Dr. Krauledat emailed Richard DePiano about Drew's delays and its lack of communication about an expected project completion date.
- 60. In October 2007, Mr. DePiano finally sent PointCare a revised timeline whose completion date of January 2008 put Drew's development schedule of the HT instrument a year behind the timeline in the original Agreement. A twelve month schedule overrun on a project

that was to be completed (by mutual agreement) within eleven months is against all industry standards and cannot be excused.

- 61. From March 2007, when the HT's design flaws were revealed, until November 2007, when PointCare served Drew with notice of termination, PointCare's research and development staff received occasional informal and non-technical e-mail updates on the redesign progress. PointCare never received any formal or informal report that Drew corrected the identified design flaws or that the HT instrument was ready for clinical testing by PointCare and FDA approval.
- 62. On November 9, 2007, PointCare served Drew with a notice of default providing the requisite 60-day cure period.
- 63. During the entire time from the return of the failed prototype to Drew in April 2007 through expiration of the cure period on January 8, 2008, PointCare cooperated fully with Drew's efforts with respect to its HT instrument and provided Drew with regular reagent shipments and promptly provided software source code upon Drew's request.
- 64. Drew engineering announced in December that they supposedly were ready to ship an HT instrument to PointCare.
- 65. PointCare's Chief Science Officer Peter Hansen asked Drew for test reports showing that the HT instrument was tested to specifications, the results of the tests and how the engineering flaws previously identified by PointCare and Drew had been corrected before accepting shipment of the instrument. The reports sought by PointCare were standard in-house reports maintained in quality control systems which must be available to show to the FDA as required by FDA regulations and the Agreement at Sections 1.3.2 and 1.3.5.

- 66. Drew failed and refused to produce these test reports or to show that the design flaws had been corrected, despite the fact that such reports are a prerequisite to FDA approval.
- 67. Moreover, even if the prototype that Drew wanted to ship to PointCare worked on December 10, there is still no way that Drew could have cured its breach within the 60-day cure period on or about January 8, 2008. Drew was so far behind schedule, and it had so many tasks left to accomplish, that Drew could not possibly cure its default within the 60-day period. .
  - 68. In short, Drew failed to cure the default.
- 69. In January 2008, Drew's attorneys forwarded to PointCare a report from Dr. Chow of Rubicon Consulting, an independent consulting firm. The Rubicon report fails to address the design flaws revealed by the testing at PointCare and fails to provide test results confirming that Drew had solved the flaws. To the contrary, the report identifies a new design flaw, specifically, that the automated mechanism failed to heat the reagents (i.e., chemicals in the assay) to the correct temperature. (see §7.4 of Rubicon report). Moreover, the Rubicon report (see § 8 of the report, "Appendix A - Requirements Not Included In This Study") inexplicably failed to test more than half of the items required before the instrument could be ready for clinical evaluation and submitted for FDA approval, as set forth in Attachment 2 to Annex 1 of the Agreement (which list the product specifications for the HT instrument). Indeed, Dr. Chow lists 3 1/2 pages of HT instrument product specification requirements that Drew has not yet tested. The vast majority of these HT instrument specifications are regarded as "mandatory." See Attachment 2 to Annex 1 of the Agreement (compare PR numbers listed in Attachment 2 to those listed in § 8 of the Rubicon/Chow report).
- According to the Rubicon report, only approximately 11 out of 63 product 70. requirements had been tested and passed. The remaining 52 either had not been tested, failed

testing, or were only partially tested. Two requirements were only partially tested because Drew had not integrated the software (even though PointCare promptly had provided the entire software source code upon Drew's request).

- 71. In summary, the Rubicon report makes it very clear that Drew has not even reached the stage of a fully integrated HT prototype and is far from completion of the HT development.
- 72. The cure required that the instrument be ready for shipment to customers. The Rubicon report makes clear that the instrument was not ready for shipment. Drew had not yet performed numerous required tests which were a prerequisite for PointCare to proceed with testing for FDA approval (which, of course, is a prerequisite for shipping to customers). Further, under Drew's own timeline, it was still many months away from having a shippable product. Even if PointCare had agreed to test the instrument, notwithstanding Drew's inexplicable failure to provide PointCare with complete test reports, the breach still would not have been cured and Drew still would have been in material breach of the contract.
- 73. With respect to PointCare's NP instrument, Drew gained no right to market the NP under the Agreement until it completed development of the HT, which it never did. Any rights of Drew to market the NP are contingent on Drew's delivery of an "approved HT" in a timely fashion, a condition Drew failed to meet, and now it can never meet because the Agreement has been properly terminated.

# **COUNT I – BREACH OF CONTRACT**

- 74. PointCare repeats and incorporates by referenced the above paragraphs.
- 75. PointCare has fully performed its obligations under the Agreement including all conditions precedent.

- 76. Drew breached the Agreement through Drew's conduct set forth herein.
- 77. PointCare has been damaged by Drew's breaches of contract.

## **COUNT II - BREACH OF COVENANT OF GOOD FAITH AND FAIR DEALING**

- 78. PointCare repeats and incorporates by referenced the above paragraphs.
- 79. By virtue of the foregoing, Drew breached the implied covenant of good faith and fair dealing.

# **COUNT III -DECLARATORY JUDGMENT**

- 80. An actual controversy exists between PointCare and Drew regarding Drew's failure to perform its responsibilities under the Agreement and PointCare's termination of the Agreement.
- 81. PointCare seeks a declaration from this Court that Drew materially breached the Agreement, Drew failed to cure its breach, PointCare properly terminated the Agreement, and Drew has no rights to Drew's NP instrument or CD4 assay.

#### PRAYER FOR RELIEF

WHEREFORE, Defendant, PointCare Technologies, Inc. prays that this Court:

- a. Enter a judgment in its favor and against Drew;
- b. Award PointCare all damages it suffered as a result of Drew's conduct as described above;
- c. Award PointCare all costs, expenses, pre- and post-judgment interest and attorneys' fees;
- d. Enter a declaratory judgment that Drew materially breached the Agreement, Drew failed to cure its breach, PointCare properly terminated the Agreement, and Drew has no rights to Drew's NP instrument or CD4 assay; and

d. Award PointCare such other and further relief as justice may require.

# **JURY DEMAND**

PointCare demands a trial by jury on all claims and issues so triable.

POINTCARE TECHNOLOGIES, INC.,

By its attorneys,

Dated: March 14, 2008

By: /s/ Howard Miller

Howard Miller, (HM:4538)

BOND SCHOENECK & KING, PLLC

1399 Franklin Avenue, Suite 200

Garden City, New York 11530-1679

Office: (516) 267-6300 Fax: (516) 267-6301

OF COUNSEL:

(Pending Pro Hac Vice Admission)

# **BURNS & LEVINSON LLP**

Andrew F. Caplan (MA Bar: #564127)

acaplan@burnslev.com

Michael P. Twohig (MA Bar: #648079)

mtwohig@burnslev.com

125 Summer Street

Boston, MA 02110

Tel: 617.345.3000 Fax: 617.345.3299

01225352